

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE DEPAKOTE: RHEALYN)
ALEXANDER, et al.,)
Plaintiffs,) Case No.
v.) 12-52-NJR-SCW
ABBOTT LABORATORIES INC.,) LEAD CONSOLIDATED
Defendants.) CASE

)

DEPOSITION OF AL C. EDWARDS, M.D.

Monday, October 3, 2016

Greenville, South Carolina

8:59 a.m.

REPORTED BY: Karen K. Kidwell, RMR, CRR

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1 BY MS. WILLIAMSON:

2 Q. All right. Doctor, if you'll flip to the
3 next page. 130. And this -- is this a January 6th,
4 1999 visit by Ms. Burnett to see you?

5 A. Yes.

6 Q. And it looks like the EEG has been done
7 since the last time you saw her; is that correct?

8 A. That's correct.

9 Q. And what was the results of that EEG from
10 what you can tell from this record?

11 A. It shows that the EEG was read as
12 abnormal. While she didn't have a bona fide seizure
13 on the EEG, which is actually kind of rare anyway,
14 she had a lot of spiking, you know, some abnormal
15 spiking wave patterns that were abnormal. And so
16 given that she was having these visual illusionary
17 kind of experiences and some of these other peculiar
18 episodes where she had lost consciousness and the
19 fact that her father and brother had both had a
20 seizure disorder, started her on low dose of
21 Depakote.

22 Q. Okay. So your treatment plan for
23 Ms. Burnett on January 6th, 1999 for a possible
24 seizure disorder was Depakote?

25 A. Yes.

1 Q. Okay.

2 A. And I just noted up there, I noticed that
3 she was not pregnant, and the risk was discussed on
4 that same note. That was in a handwritten note.

5 Q. Okay. Where is that?

6 A. It says, "List all other current
7 medications and substances (center and non-center)."
8 It says, "Negative pregnant, P-R-E-G, risk
9 discussed."

10 Q. Okay. Doctor, was Depakote the first
11 medication you had prescribed to Ms. Burnett for
12 treatment of seizures?

13 A. Yes.

14 Q. To your knowledge, had Ms. Burnett been on
15 any medications in the past for treatment of
16 seizures?

17 A. No. I did not know that, that she -- if
18 she had.

19 Q. Okay. All right, Doctor, if you'll flip
20 to 129?

21 A. Okay.

22 Q. And is this a January 13th, 1999 visit by
23 Ms. Burnett to you?

24 A. Yes.

25 Q. Okay. And how is she doing at this visit?

1 and try to pick the one that, you know, we think
2 might be the best. So I probably did, but I can't
3 swear to you that I did.

4 Q. Okay. And do you -- as you sit here right
5 now, are there other medications that would have kind
6 of served those dual purposes that you prescribed
7 Depakote for that you can think of that would have
8 been other treatments that, you know, would have come
9 to mind for you at that time?

10 A. Not so many dual purpose drugs like that.

11 Q. All right. So as we think about the
12 reason that you prescribed Depakote for Ms. Burnett
13 in the, you know, January 1999 time frame, is it fair
14 to say that, for her, at that time, for the
15 conditions that you were prescribing to treat for
16 her, that Depakote was the only reasonable choice
17 that you would have considered at that time?

18 MS. WILLIAMSON: Object to the form.

19 Leading. Mischaracterizes prior testimony.

20 THE WITNESS: I think it was certainly
21 one -- it was -- there wasn't any other dual
22 purpose drugs that I'm real familiar with that
23 would potentially do that same thing.

24 BY MR. EVANS:

25 Q. Okay. All right. And there was some

1 least the first several paragraphs of the uses in
2 pregnancy section are in all caps?

3 A. Yes.

4 Q. Okay. Did the information that appeared
5 in all caps in a PDR signify anything to you as a
6 prescribing doctor back in 1999?

7 A. I think it was just calling attention to,
8 yeah, emphasizing a problem.

9 Q. Okay. So just yet another way to
10 emphasize a problem, right?

11 MS. WILLIAMSON: Object to the form.

12 THE WITNESS: That's the way I would
13 interpret it, yes.

14 BY MR. EVANS:

15 Q. All right. And you read -- well, first of
16 all, it says that "According to published and
17 unpublished reports, valproic acid may produce
18 teratogenic effects." And you understood that
19 Depakote could cause birth defects in 1999, right?

20 A. Yes.

21 Q. Okay. Doctor, can you read the last
22 sentence of that first paragraph again, please?

23 A. "For use in pregnant"?

24 Q. It says, "in use," yeah. The one that
25 starts with "Although data"?

1 anomalies." Do you see that, right after the
2 paragraph "Uses in Pregnancy" that --

3 A. Yes.

4 Q. Okay? All right. And it says that,
5 "Other congenital anomalies, e.g., cranial facial
6 defects, cardiovascular malformations and anomalies
7 involving various body systems, compatible and
8 incompatible with life, have been reported."

9 A. Yes.

10 Q. Right? So that's -- in addition to
11 discussing specific birth defects, it also indicates
12 that there's a risk of death to the fetus?

13 A. That's correct.

14 Q. That's a really significant risk, right?

15 A. That would be, yes.

16 Q. Okay. All right. So you would have known
17 in 1999 that Depakote could cause birth defects
18 besides neural tube defects including cleft palate,
19 heart defects, limb defects, right?

20 MS. WILLIAMSON: Object to form.

21 THE WITNESS: Yes.

22 BY MR. EVANS:

23 Q. All right. And that would have been
24 significant to your risk-benefit analysis -- excuse
25 me -- that would have been significant to your

1 risk-benefit analysis in the 1999 time frame,
2 correct?

3 A. Sure.

4 Q. Now, I think there is some indication that
5 the paragraph we just read -- it goes on to say here,
6 that "Significant data to determine the incidence of
7 these congenital anomalies is not available," right?

8 A. Right.

9 Q. That's what it says. Okay. Is it -- is
10 it uncommon for medications that you were prescribing
11 in the 1999 time frame, for there to be no specific
12 information provided about the incidence of the -- of
13 the -- the potential adverse effect?

14 And I could be more -- kind of be a little
15 bit more specific. Clozaril, which is the medication
16 you prescribed for -- for Ms. Burnett, right?

17 A. Right.

18 Q. Okay. Clozaril has a very significant
19 risk of a condition called agranular cytosis?

20 A. That's right.

21 Q. Right. That was a really significant risk
22 that was actually described in a black box warning?

23 A. That's right.

24 Q. Back in 1999, right?

25 A. Yes.

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1 It's unfortunately that she became pregnant.
2 That's an unfortunate thing. She was one of the
3 few people that took -- actually was a fairly
4 low dose of Depakote and ended up with a baby
5 with this problem.

6 If the risk to her fetus had been
7 50 percent, 25 percent as opposed to 1 percent,
8 could that have influenced my decision to
9 prescribe Depakote to her? Yes, it could have.
10 Would it absolutely have done that? Maybe not.

11 BY MR. EVANS:

12 Q. Fair to say you just don't know as you sit
13 here today whether or not it would have -- it would
14 have -- it would have changed your decision to
15 prescribe or not?

16 A. I do not know that.

17 Q. Okay. All right. And I think as you told
18 us, in reality for Ms. Burnett in terms of the
19 drilling down on the reason you were prescribing
20 Depakote for her, and there was these two-fold
21 reasons, right?

22 A. Correct.

23 Q. There was the seizure disorder and then
24 there was also the schizoaffective disorder, right?

25 A. That's correct.

1 Q. I mean, there -- the reality is that she
2 needed treatment, correct?

3 A. Yes.

4 Q. Okay. And Depakote may very well have
5 been the only reasonable treatment for her condition
6 at that time?

7 MS. WILLIAMSON: Object to the form.

8 Leading. Asked and answered.

9 THE WITNESS: It was one that seemed to be
10 a more simple regimen and has potential benefit.
11 I mean, whether one could construct a different
12 treatment regimen to come out with the same
13 result, it would have been more complex and
14 maybe just as risky.

15 BY MR. EVANS:

16 Q. Certainly as you sit here right now, you
17 can't say that there was another, you know, treatment
18 regimen that you thought was a more reasonable
19 treatment regimen than the Depakote?

20 MS. WILLIAMSON: Object to form. Asked
21 and answered. Mischaracterizes prior testimony.

22 THE WITNESS: That's right.

23 BY MR. EVANS:

24 Q. All right, Doctor. Let's run through some
25 records with you.

1 CERTIFICATE OF REPORTER

2 I, Karen K. Kidwell, Registered Merit
3 Reporter and Notary Public for the State of South
Carolina at Large, do hereby certify:

4 That the foregoing deposition was taken
5 before me on the date and at the time and location
6 stated on page 1 of this transcript; that the
7 deponent was duly sworn to testify to the truth, the
whole truth and nothing but the truth; that the
8 testimony of the deponent and all objections made at
the time of the examination were recorded
9 stenographically by me and were thereafter
transcribed; that the foregoing deposition as typed
is a true, accurate and complete record of the
testimony of the deponent and of all objections made
at the time of the examination to the best of my
ability.

10 I further certify that I am neither related
11 to nor counsel for any party to the cause pending or
interested in the events thereof.

12 Witness my hand this 10th day of October, 2016.

13

14

15

Karen K. Kidwell,

Registered Merit Reporter

16

Notary Public

17

State of South Carolina at Large

18

My Commission expires:

19

August 21, 2024

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